| IN THE UNITED STATES PATENT AND TRADEMARK OFFICE | | |
|---|---|---|
| | *Application No.* | **09/125,114** |
| | *Filing Date* | **AUGUST 18, 1998** |
| | *First Named Inventor* | **PRICE** |
| | *Group Art Unit* | **1617** |
| | *Examiner Name* | **Shaojia A. Jiang** |
| | *Attorney Docket No.* | **2955-101** |
| *Title of the Invention:* **DOSAGE FORM OF IBUPROFEN** | | |

#42



**PETITION TO WITHDRAW HOLDING OF ABANDONMENT**

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Applicant has received a Notice of Abandonment dated June 18, 2003 in which the above-referenced case has been declared abandoned for failure to respond to an Office letter dated August 18, 2002 (hereinafter the "Office Action").

Applicant submits that the Notice of Abandonment incorrectly states that an Office Action was mailed on August 18, 2002, the correct mailing date for this Office Action is October 18, 2002. Applicant further submits that a response has been filed with the U.S. Patent and Trademark Office (USPTO) within the 3 month response period on January 21, 2003, January 18, 2003 being a Saturday and January 20, 2003 being a Federal Holiday (Martin Luther King Day). Applicant submits that the documents attached hereto are sufficient to prove that Applicant's representative has responded to the Office Action on January 21, 2003.

To review, the USPTO mailed an Office Action on October 18, 2002 to Applicant at the correspondence address of Arent Fox Kintner Potkin & Kahn PLLC, the firm responsible for handling the current application at the time. On January 21, 2003 Applicant responded to the Office Action and included with his response an Associate Power of Attorney with Revocation of Previous Power and Change of Correspondence Address. The new correspondence address is the

address of Rothwell, Figg, Ernst & Manbeck PC, the firm currently responsible for handling the current application.

It is noted that the Examiner in charge of the case has inquired if the current application was abandoned by telephonic interview with Mr Robert K. Carpenter of the Arent Fox Kintner Potkin & Kahn PLLC firm, on May 29, 2003. It is further noted that at that time the firm of Rothwell, Figg, Ernst & Manbeck PC was responsible for prosecuting the current application, and was not informed of the call to Mr Carpenter. The interview summary states that no reply from Applicant was received and the application was technically abandoned. The Notice of Abandonment was mailed to Arent Fox Kintner Potkin & Kahn PLLC on June 18, 2003. The firm of Rothwell, Figg, Ernst & Manbeck PC received the Notice of Abandonment on June 26, 2003.

Attached are copies of the Notice of Abandonment mailed June 18, 2003, the Associate Power of Attorney with Revocation of Previous Power and Change of Correspondence Address filed January 21, 2003, the response to the Office Action filed January 21, 2003, and the return postcard with the Patent Office's Stamp thereon acknowledging receipt on January 21, 2003.

The above demonstrates that Applicant timely filed a response to the Office Action mailed October 18, 2002 on January 21, 2003 together with a Change of Correspondence Address and an Associate Power of Attorney. Thus, it is respectfully submitted that the assertion of failure to reply to the October 18, 2002, Office Action and the technical holding of abandonment by the USPTO is incorrect and not the fault of the Applicant in any way.

Therefore, it is respectfully requested that any holding of abandonment be withdrawn. See MPEP §711.02 and MPEP §711.03. Any fees associated with this communication should be

waived since the evidence submitted herewith shows that Applicant is in no way at fault. Applicant timely responded to the Office Action mailed October 18, 2002.

Should withdrawal from abandoned status not be granted immediately; this Petition should be considered to be a Petition to the Commissioner under 37 C.F.R. §§1.181-1.183, including a petition that all fees in connection therewith be waived because it is clear that Applicant is not at fault in this matter.

Should any such petition under 37 C.F.R. §§1.181-1.183 not be immediately granted, this Request should be considered to be a Petition under (37 C.F.R. §1.137(a) or §1.137(b)), including a petition that all fees in connection therewith be waived because it is clear that Applicant is not at fault in this matter.

Should the appropriate official of the U.S. Patent and Trademark Office have any questions, that official is requested to telephone Applicant's undersigned attorney.

| RESPECTFULLY SUBMITTED, | | | | | |
|---|---|---|---|---|---|
| NAME AND REG. NUMBER | Willem F.C. de Weerd, Registration No. 51,613 | | | | |
| SIGNATURE | | | | DATE | July 1, 2003 |
| ADDRESS | Rothwell, Figg, Ernst & Manbeck<br>1425 K Street, N.W., Suite 800 | | | | |
| CITY | Washington | STATE | D.C. | ZIP CODE | 20005 |
| COUNTRY | U.S.A. | TELEPHONE | (202) 783-6040 | FAX | (202) 783-6031 |

**Attachments: Notice of Abandonment**
**Copy of the Associate Power of Attorney with Revocation of Previous Power and Change of Correspondence Address filed January 21, 2003**
**Copy of Response to Office Action filed January 21, 2003**
**Copy of Return Postcard with the Patent Office's Stamp thereon**

1617

# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

| *Complete if Known* | |
|---|---|
| Application Number | 09/125,114 |
| Filing Date | August 18, 1998 |
| First Named Inventor | PRICE |
| Examiner Name | Shaojia A. Jiang |
| Group Art Unit | 1617 |
| Total Number of Pages in This Submission 4 | Attorney Docket Number 2955-101 |

**ENCLOSURES *(check all that apply)***

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Request for Reconsideration
  - ☐ After Final
  - ☐ Declaration under Rule 312
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☒ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s)

REMARKS:

- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*:

(1) Notice of Abandonment
(2) Copy of Associate Power of Attorney with Revocation of Previous Power and Change of Correspondence Address filed January 21, 2003
(3) Copy opf Response to Office Action filed January 21, 2003
(4) Copy of Return Postcard with Patent Office's Stamp thereon

| SUBMITTED BY | | | | Complete (if applicable) | |
|---|---|---|---|---|---|
| NAME AND REG. NUMBER | Willem F.C. de Weerd, Reg. No.51,613 | | | | |
| SIGNATURE | | DATE | 7/1/03 | DEPOSIT ACCOUNT USER ID **02-2135** | |

**THE PATENT OFFICE'S STAMP HEREON IS ACKNOWLEDGMENT BY IT OF RECEIPT OF THE FOLLOWING IN REGARD TO:**

ATTORNEY DOCKET NO. 2955-101
ATTORNEY/TYPIST INITIALS RM:WDW:maf
DUE DATE January 18, 2003

SERIAL/PATENT NO. 09/125,114
FILED/ISSUED August 18, 1998
APPLICANT/PATENT PRICE

**DOCUMENTS ATTACHED:**

**AMENDMENT AND REQUEST FOR RECONSIDERATION,** with Associate Power of Attorney with Revocation of Previous Power and Change of Correspondence Address attached.


5 of 29

Fyi

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov



| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/125,114 | 08/18/1998 | IAN ASHLEY PRICE | P8129-8004 | 7439 |

7590 06/18/2003

FOLEY & LARDNER
ARENT, FOX, KINTNER, PLOTKIN & KAHN, P.L.L.C.
1050 CONNECTICUT AVENUE, N.W.
SUITE 600
WASHINGTON, DC 20036-5339

| EXAMINER |
|---|
| JIANG, SHAOJIA A |

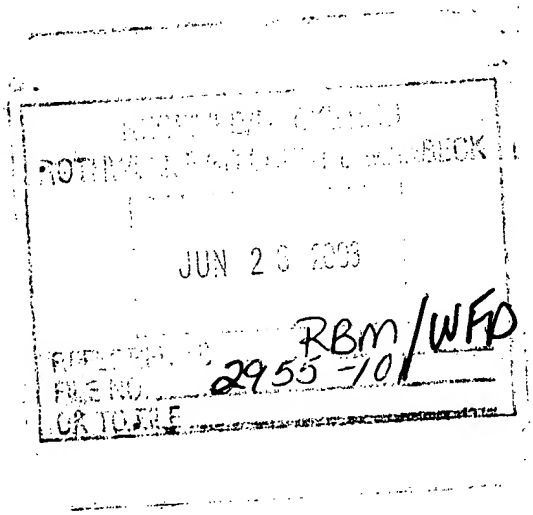
| ART UNIT | PAPER NUMBER |
|---|---|
| 1617 | |

DATE MAILED: 06/18/2003

36

Please find below and/or attached an Office communication concerning this application or proceeding.





# Notice of Abandonment

| Application No. | Applicant(s) | |
|---|---|---|
| 09/125,114 | PRICE, IAN ASHLEY | |
| **Examiner** | **Art Unit** | |
| Shaojia A. Jiang | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--*

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 18 August 2002. 10/18/02 CWS 6-30-03
   (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
   (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
   (A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
   (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
   (d) ☒ No reply has been received.

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
   (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
   (b) ☐ The submitted fee of $_____ is insufficient. A balance of $_____ is due.
   The issue fee required by 37 CFR 1.18 is $_____. The publication fee, if required by 37 CFR 1.18(d), is $_____.
   (c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
   (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
   (b) ☐ No corrected drawings have been received.

4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.

6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

7. ☐ The reason(s) below:

SREENI PADMANABHAN
PRIMARY EXAMINER 6/17/03

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

# Interview Summary



| Application No. | Applicant(s) | |
|---|---|---|
| 09/125,114 | PRICE, IAN ASHLEY | |
| Examiner | Art Unit | |
| Shaojia A. Jiang | 1617 | |

All participants (applicant, applicant's representative, PTO personnel):

(1) *Shaojia A. Jiang*. (3)_____.

(2) *Mr. Robert K. Carpenter*. (4)_____.

Date of Interview: *29 May 2003*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *none*.

Identification of prior art discussed: *none*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *The examiner inquired if the instant application is abandoned. No reply to this inquiry is from Applicant. Therefore, the instant application is technically abandoned.*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

5/29/03
Examiner's signature, if required

# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

| *Complete if Known* | |
|---|---|
| Application Number | 09/125,114 |
| Filing Date | August 18, 1998 |
| First Named Inventor | PRICE |
| Group Art Unit | 1617 |
| Examiner Name | Alysia Berman |
| Total Number of Pages in This Submission 13 | Attorney Docket Number 2955-101 |



**ENCLOSURES *(check all that apply)***

- ☐ Fee Transmittal Form
- ☐ Fee Attached
- ☒ Amendment/Reply
- ☐ After Final
- ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
- ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
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- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) *(please identify below)*:

REMARKS:

| SUBMITTED BY | | | | Complete (if applicable) | |
|---|---|---|---|---|---|
| NAME AND REG. NUMBER | Willem F.C. de Weerd, Registration No. 51,613 | | | | |
| SIGNATURE | | DATE | Jan. 21, 2003 | DEPOSIT ACCT USER ID | 02-2135 |

I:\DATA\Clients\2955\2955-101.trn

| | | |
|---|---|---|
| IN THE UNITED STATES PATENT AND TRADEMARK OFFICE | Application Number | 09/125,114 |
| | Filing Date | August 18, 1998 |
| | First Named Inventor | PRICE |
| | Group Art Unit | 1617 |
| | Examiner Name | Alysia Berman |
| | Attorney Docket Number | 2955-101 |
| Title: DOSAGE FORM OF IBUPROFEN | | |



## AMENDMENT AND REQUEST FOR RECONSIDERATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the Office Action dated October 18, 2002 (January 18, 2003 being a Saturday and Monday, January 21, 2003 being a federal holiday), please amend the above-identified U.S. patent application as follows:

**IN THE CLAIMS:**

Please amend claims 1, 16 and 26 as shown on the following pages.

Marked-up copies of the original text of the amended claims are attached to this amendment. Material inserted is indicated by underlining (insertion) and material deleted is indicated by bracketing ([deletion]).

**Clean Copy of Amended Claims 1, 16 and 26**

1. A solid non-effervescent compressed dosage form suitable for oral administration and adapted to disintegrate quickly in the gastro-intestinal tract comprising a racemic ibuprofen medicament present to an extent of 35% or more by weight to the dosage form and in homogeneous admixture with a carrier material comprising

i) a compressible filler component combined with a disintegrating component;

ii) 3-20% solid alkali metal carbonate or bicarbonate by weight of the dosage form;

wherein the dosage form is obtained by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa such that said dosage form has a crushing strength in the range 6.5-15 Kp and a disintegration time of less than 10 minutes, provided that the ibuprofen medicament does not contain a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

16. A method of obtaining an onset-hastened analgesic and/or anti-pyretic response comprising the oral administration of a non-effervescent compressed solid dosage form adapted to disintegrate quickly in the gastro-intestinal tract comprising 35% or more by weight of a racemic ibuprofen medicament in homogeneous admixture with a carrier material comprising

i) a compressible filler component combined with a disintegrating component and

ii) 3-20% solid alkali metal carbonate or bicarbonate by weight of the dosage form,

wherein the dosage form is obtained by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa such that said dosage form has a crushing strength in the range 6.5-15 Kp and a disintegration time of less than 10 minutes, provided that the ibuprofen medicament does not include a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

26. A solid formulation suitable for oral administration and adapted to disintegrate quickly in the gastro-intestinal tract, said solid formulation having a layer comprising a compressed composition comprising a racemic ibuprofen medicament in homogeneous admixture with a carrier material comprising, the racemic ibuprofen medicament being present to an extent of 35% or more by weight of the composition and the carrier material comprising a compressible filler component combined with a disintegrating component characterised in that the carrier material comprises 3-20% solid alkali metal carbonate or bicarbonate by weight of the dosage form wherein the compressed composition is obtained by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa to provide a layer having a crushing strength in the range 6.5-15 Kp and a disintegration time of less than 10 minutes.

## REMARKS

In an Office Action dated October 18, 2002, claims 1-10, 16-19, 26, 30 and 31, all of the claims under consideration in the subject patent application, were rejected. By amendment above, independent claims 1, 16 and 26 have been rewritten. Support for the amendments in claims 1, 16 and 26 can be found on page 1, line 25 of the specification.

Reconsideration of this application and allowance of the claims is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 1-10, 16-19, 26, 30 and 31 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner indicated that it is unclear if the dosage form is formed at a compression force above 80 MPa or if it disintegrates in less than 10 minutes when subjected to a compression force above 80 MPa. Independent claims 1, 16 and 26 have been amended to more clearly define the subject matter of the invention, wherein the dosage form is obtained by compression at a compression force above 80 MPa.

Claims 1-10, 16-19, 26, 30 and 31 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over US 5,380,535 (Greyer et al) in combination with US 4,844,907 (Elgar et al).

The invention of the present application as claimed in claim 1 is directed to a solid non-effervescent compressed dosage form suitable for oral administration and adapted to disintegrate quickly in the gastro-intestinal tract, thereby permitting delivery of high therapeutic levels of ibuprofen (greater than *or* equal to 35% by weight of the composition) to a patient. In particular

this is achieved by including 3 to 20% by weight of an alkali metal (bi)carbonate in the composition.

The inclusion of an alkali metal (bi)carbonate enhances the compressibility of the compressible filler and disintegrant in the pharmaceutical composition of the present invention. Conveniently, this permits a reduction in the amount of compressible filler component that would normally be required in a comparable composition not including an alkali metal (bi)carbonate. Thus, an acceptably sized tablet may be produced which a patient may swallow easily to permit delivery of the ibuprofen medicament to the gastro-intestinal tract.

In addition, unexpectedly the inclusion of an alkali metal (bi)carbonate in the composition of the present invention enables a dosage form to be produced by standard tabletting machines (i.e., at a compression force above 80 MPa), such that the dosage form not only has an acceptable relatively fast disintegration time to permit an on-set hastened action but also exhibits desired hardness so that the dosage forms do not break up during manufacture and during oral administration to a patient. Contrary to the examiner's opinion these parameters are critical to the invention, because in combination they permit the ibuprofen to be delivered to the gastro-intestinal tract and a rapid onset of therapeutic action (see page 1, final paragraph). As stated in the present application, the unexpected finding of improved hardness coupled with desirable disintegration times is contrary to the teaching of the prior art (see page 2, second paragraph).

In contrast to the invention as now claimed, Greyer et al. is directed to providing a completely different solution to a completely different technical problem and thus actively teaches away from the invention of the present application. Greyer et al. is directed to delivering an unpleasant tasting medicament to a patient who has difficulty swallowing a tablet or capsule (see column 1, lines 60 onwards). Greyer et al. solves this problem by providing a chewable composition which disintegrates rapidly in the mouth (see column 2, lines 24 to 26). Greyer et

al. is not concerned whatsoever with providing a hard solid dosage form which when swallowed exhibits a relatively rapid disintegration time in the gastro-intestinal tract.

Suitably, it is most unlikely that a skilled person on reading Greyer et al. would firstly take the non-obvious steps of including a buffering agent in the composition generally disclosed (column 8) or the specific Example 5, then take the next non-obvious step of selecting sodium bicarbonate from a general list of buffering agents, and finally be motivated to compress the mixture in the expectation of forming an acceptably sized dosage form having improved hardness properties so that it may be swallowed easily and then disintegrate relatively rapidly in the gastro-intestinal tract, as Greyer et al. is concerned only with producing chewable dosage forms that disintegrate in the mouth, and thus actively teaches away from forming a solid dosage form which may be swallowed to deliver a medicament to the gastro-intestinal tract.

Moreover, nowhere does Greyer at al teach or suggest that the inclusion of an alkali metal (bi)carbonate would, let alone could, provide an improved compressed dosage form having the claimed hardness and disintegration time, thereby permitting formation of an acceptably sized tablet to allow large doses of ibuprofen to be delivered to the gastro-intestinal tract. Greyer et al. merely mentions at column 6 that sodium bicarbonate is one of a number of buffering agents which may be used to eliminate the burning in the throat caused by ibuprofen i.e., when delivering ibuprofen to the mouth rather than the gastro-intestinal tract.

Furthermore, in Greyer et al. the pharmaceutical composition is in a lipid formulation forming an oral chewable drug delivery system to which may be added a buffering agent such as an alkali metal (bi)carbonate. The current application is directed to a hard tablet exhibiting on-set hastening release in the gastro-intestinal tract, which tablet is obtained through compressing the composition at a compression force of above 80 MPa. Greyer et al. however, do not teach

anything with respect to the compression of the ibuprofen composition or a compression force used to obtain the hard tablet in which the alkali metal (bi)carbonate increases the compressibility and reduces the amount of filler required. Therefore, a skilled person on reading Greyer et al. is not motivated to include an alkali metal (bi)carbonate to produce a hard ibuprofen tablet obtained by compression above 80 MPa, resulting in an on-set hastened ibuprofen release in the gastro-intestinal tract. This deficiency is not cured by Elgar et al, which discloses a pharmaceutical composition in the form of a multi-phase tablet. In Elgar et al. tableting is obtained through a self-lubricating compression aid wherein the self-lubricating compression aid is preferably microcrystalline cellulose, a compound very different than an alkali metal (bi)carbonate as in the present invention. Therefore, Elgar et al. is teaching away from using an alkali metal (bi)carbonate to increase compressibility and reduce filler, allowing compression into a hard tablet or a layer in a pharmaceutical formulation at a compression force of above 80 MPa, as Elgar et al. is teaching the use of microcrystalline cellulose as a compression aid, to compress a pharmaceutical composition into a tablet layer. Thus, Greyer et al. in view of Elgar et al. does not teach or suggest the present invention, but in fact is teaching away from the invention of the current application.

Applicant respectfully submits that the claimed invention in claims 1-10, 16-19, 26, 30 and 31 therefore is not obvious over US 5,380,535 (Greyer et al) in combination with US 4,844,907 (Elgar et al.). Withdrawal of the rejection is respectfully requested.

Claims 1-10, 16-19, 26, 30 and 31 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over US 5,380,535 (Greyer et al) in combination with US 5,262,179 (Gregory et al).

Greyer et al. does not teach or suggest the subject matter of the present invention as discussed above. In addition, Gregory et al. is directed to dry powder water-soluble ibuprofen salts wherein the unpleasant taste is masked by incorporating a taste masking amount of an alkali metal bicarbonate. The disclosure of Gregory et al. is not directed to hard tablets and teaches only the use of alkali metal bicarbonates in dry powder water-soluble ibuprofen. The disclosure in Gregory et al. is silent with respect to the compression into hard tablets of an ibuprofen composition as it is directed to a dry powder, thus effectively teaching away from using these alkali metal bicarbonates in ibuprofen containing hard tablets. The inclusion of these alkali metal (bi)carbonates, increasing the compressibility of the composition of the present invention while reducing the amount of pharmaceutical fillers, enables compression into hard tablets at a compression force of above 80 MPa, forming hard ibuprofen tablets with an on-set hastened release of ibuprofen in the gastro-intestinal tract. These unexpected characteristics of increased compressibility with a reduction of filler and the on-set hastened release in the gastro-intestinal tract of the hard tablet by inclusion of alkali metal (bi)carbonates are not taught or suggested by Gregory et al. Moreover, there is no motivation in Greyer et al. (a chewable tablet dosage form) or in Gregory et al. (a dry powder dosage form) either alone or in combination to compress the composition into a hard ibuprofen tablet with the inclusion of an alkali metal (bi)carbonate as is the subject matter of the present invention. Thus, Greyer et al. in view of Gregory et al. does not teach or suggest the present invention.

Applicant respectfully submits that the claimed invention in claims 1-10, 16-19, 26, 30 and 31 therefore is not obvious over US 5,380,535 (Greyer et al) in combination with US 5,262,179 (Gregory et al). Withdrawal of the rejection is respectfully requested.

Applicant submits that the Examiner's assertion that the current application names joint inventors is incorrect, as Ian A. Price is the sole inventor of the current application. The subject matter of the claims in the present application therefore was solely made by applicant at the time any inventions covered herein were made.

Applicant submits that the present application is now in condition for allowance. Reconsideration and favorable action are earnestly requested.

| RESPECTFULLY SUBMITTED, | | | | | |
|---|---|---|---|---|---|
| NAME AND REG. NUMBER | Willem F.C. de Weerd, Registration No. 51,613 | | | | |
| SIGNATURE | | | | DATE | Jan. 21, 2003 |
| *Address* | Rothwell, Figg, Ernst & Manbeck<br>1425 K Street, N.W., Suite 800 | | | | |
| *City* | Washington | *State* | D.C. | *Zip Code* | 20005 |
| *Country* | U.S.A. | *Telephone* | 202-783-6040 | *Fax* | 202-783-6031 |

2955-101.am1

**Amended Claims 1, 16 and 26: Version with markings to show changes made**

1. (Amended) A solid non-effervescent compressed dosage form suitable for oral administration and adapted to disintegrate quickly in the gastro-intestinal tract comprising a [homogeneous admixture of] racemic ibuprofen medicament present to an extent of 35% or more by weight to the dosage form and in homogeneous admixture with a carrier material comprising

i) a compressible filler component combined with a disintegrating component;

ii) 3-20% solid alkali metal carbonate or bicarbonate by weight of the dosage form;

wherein the dosage form is obtained by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa such that said dosage form has a crushing strength in the range 6.5-15 Kp and a disintegration time of less than 10 minutes [at a compression force above 80 MPa], provided that the ibuprofen medicament does not contain a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

16. (Amended) A method of obtaining an onset-hastened analgesic and/or anti-pyretic response comprising the oral administration of a non-effervescent compressed solid dosage form adapted to disintegrate quickly in the gastro-intestinal tract comprising 35% or more by weight of a racemic ibuprofen medicament in homogeneous admixture with a carrier material comprising

i) a compressible filler component combined with a disintegrating component and

ii) 3-20% solid alkali metal carbonate or bicarbonate by weight of the dosage form,

wherein the dosage form is obtained by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa such that said dosage form has a crushing strength in the range 6.5-15 Kp and a disintegration time of less than 10 minutes [at a compression force of above 80 MPa], provided that the ibuprofen medicament does not include a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

26. (Amended) A solid formulation suitable for oral administration and adapted to disintegrate quickly in the gastro-intestinal tract, said solid formulation having a layer comprising a compressed composition comprising a racemic ibuprofen medicament in homogeneous admixture with a carrier material, the racemic ibuprofen medicament being present to an extent of 35% or more by weight of the composition and the carrier material comprising a compressible filler component combined with a disintegrating component characterised in that the carrier material comprises 3-20% solid alkali metal carbonate or bicarbonate by weight of the dosage form wherein the compressed composition is [capable of compression] obtained by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa to provide a layer having a crushing strength in the range 6.5-15 Kp and a disintegration time of less than 10 minutes [at a compression force above 80 MPa].

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| | Filing Date | August 18, 1998 |
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| | Examiner Name | Alysia Berman |
| | Attorney Docket Number | 2955-101 |
| Title: DOSAGE FORM OF IBUPROFEN | | |

## ASSOCIATE POWER OF ATTORNEY WITH REVOCATION OF PREVIOUS POWER AND CHANGE OF CORRESPONDENCE ADDRESS

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Power of Attorney and Revocation

The undersigned hereby appoints the practitioners associated with **Customer Number 6449** as associate attorneys to prosecute the application identified above, and transact all business in the Patent and Trademark Office connected therewith. All previous powers of attorney are hereby revoked.

Change of Correspondence Address

Please change the correspondence address for the above-identified application to:

**Customer Number 6449**

| RESPECTFULLY SUBMITTED, | | | | | |
|---|---|---|---|---|---|
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